UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,271	12/12/2003	Tomomi Sugiyama	11333/31	3598

757 7590 04/08/2008

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
WRIGHT, PATRICIA KATHRYN	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
04/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,271	SUGIYAMA, TOMOMI	
	Examiner	Art Unit	
	P. Kathryn Wright	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed December 05, 2007 in which 1, 4-5, 7, 12 and 17 were amended and claims 20-24 were canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated June 05, 2007 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed. Any objection/rejection not repeated herein has been withdrawn by the Office.

Claims 1-19 are currently under prosecution.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “analyzer identification information”, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. 37 CFR 1.72(b) requires that the abstract be set forth on *a separate sheet*. This requirement *applies to amendments to the abstract* as well as to the initial filing of the application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recite a "storage means for storing" and a "control means for correcting". As pointed out in the previous Official action, both limitations use the language "means for". Furthermore, the "means for" is not modified by sufficient structure, material or acts for achieving the specified function. Thus, these claim limitations are being treated by the Office under 35 U.S.C. 112, sixth paragraph. Where means plus function language is used to define the characteristics of a machine or manufacture invention, such language *must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof" that correspond to the recited function*.

In the Reply filed December 05, 2007, Applicant defines the "storage means for storing" embodied by the "examination information database 12", and the "control means for determining" is embodied by the "CPU 71 of server 1". However, the specification itself fails to set forth an adequate disclosure showing what is meant by the means plus function language.

Since applicant failed to set forth an adequate disclosure, applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112. Applicant should amend the specification to set forth an adequate disclosure showing what is meant by the means plus function language.

Furthermore, claims 1 and 12 recite a management apparatus comprising, *inter alia*, an analyzer identification information for identifying whether or not the analyzer for the assay has a dilution mode. The specification does support a bar code *on the sample container* which indicates the type of analyzer used at page 19, lines 2-5. However, the specification does not disclose what the "analyzer identification information" corresponds to.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-9 and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandler et al. (US Patent No. 6,275,150), hereinafter "Mandler".

Mandler teaches a clinical laboratory management system comprising a plurality of analyzers 20a-c for analyzing samples outputting a result of an assay (see Fig. 16) and a management apparatus connected to the analyzers through a network 30 (see Fig. 1).

The management apparatus of Mandler comprises at least one storage means (e.g., database) in the computer (i.e., control means 10). Note that all storage means are configured for storage, thus, the storage in the reference need only be capable of storing the same type of data (i.e., dilution rate and sample identification information).

Nevertheless, Mandler does in fact teach a storage means configured to store a result of the assay output from the analyzers , analyzer identification information (e.g., ADVIA2, ADVIA3, etc), and the sample identification information including whether or not the pre-dilution module 24 performs any dilution or whether it is required (see col. 3, line 20- col. 4, line 7).

The management apparatus of Mandler also includes a control means 10 configured for determining whether the analyzers has a dilution module 24 in which the dilution mode (PD) is in the "READY" or "OFF" state, as indicated by the status buttons 288, see Fig. 5 and col. 6, lines 6-60. That is, Mandler teaches a system where one of the analyzers 20a-c can be in the "OFF" state (i.e., no dilution mode) and the other analyzer is available (i.e., has a dilution mode). The control means uses a dilution factor and calculates the dilution rate of the sample with the result of the sample used in the assay (see "Dil" column in Fig. 16 and col. 13, lines 11-41). The Mandler control means 10 also determines whether any pre-dilution of the sample is required when information is input into the system (see col. 3, line 65- col. 4, line 7). The control means displays various screens (GUI) designed to receive, among other things, the quantity of the sample used in the assay.

Mandler also teaches a printing device (printer 12). Since all printers are configured for printing, the printer in the reference need only be capable of printing the same type of data (i.e., dilution rate and sample identification information).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mandler et al. (US Patent No. 6,275,150) in view of EP 1 107 159 to Okuno et al., (hereinafter "Okuno").

The teachings of Mandler have been summarized above. While Mandler does teach a screen for receiving sample identification information, Mandler does not explicitly teach the sample information is printed as a bar code. However, the use of bar codes for storing sample information in an analyzer system is considered conventional, see for example Okuno.

The teachings of Okuno have been summarized in the previous Official action, dated June 05, 2007. Okuno teaches a clinical laboratory management system comprising a plurality of analyzers 2 for analyzing samples and a management apparatus connected to the analyzers (see Fig. 1). The management apparatus of Okuno comprises, *inter alia*, sample identification information printed as a bar code (see par. 0091]).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to supply the sample identification information of Mandler in the form of a bar code, as taught in Okuno, since bar codes are generally not readable by humans, therefor can be used to provide patient anonymity.

Response to Arguments

13. Applicant's arguments filed December 05, 2007 have been fully considered but they are not persuasive.

In response to the rejection of claims 1-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, Applicant defines the “storage

means for storing" embodied by the examination information database 12 and the "control means for determining" embodied by the "CPU 71 of server 1 (claims 1 and 12). However, the specification itself fails to set forth an adequate disclosure showing what is meant by the means plus function language.

Claims 1 and 12 recite a "storage means for storing" and a "control means for determining". Both limitations use the language "means for". Furthermore, the "means for" is not modified by sufficient structure, material or acts for achieving the specified function. Thus, these claim limitations are being treated by the Office under 35 U.S.C. 112, sixth paragraph. Where means plus function language is used to define the characteristics of a machine or manufacture invention, such language *must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof" that correspond to the recited function*.

However, as pointed out above, Applicant failed to set forth an adequate disclosure in the specification, thus, applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112. Applicant should amend the specification to set forth an adequate disclosure showing what is meant by the means plus function language.

Furthermore, claims 1 and 12 recite a "storage means configured for storing… analyzer identification information for identifying whether or not the analyzer for the assay has a dilution mode"… The Examiner maintains that the specification does not adequately disclose what element in the specification the "analyzer identification information" corresponds to.

Applicant points to page 13, lines 6-15 and Fig. 2 for support of the "analyzer identification information for identifying whether or not the analyzer used for the assay has a dilution mode." Page 13, lines 6-15 states "FIG. 2 shows the table of the examination information database **12.** Records are prepared for each received examination, and examination information, including the 'reception number,' 'patient name', 'patient ID', 'rush **10** examination status', 'examination item', and 'sample and analyzer specification codes' for specifying the type of sample and analyzer used are input and stored in the examination information database **12** at the time of reception. Furthermore, the time at which the reception is **15** input is also stored." The Examiner believes that the "sample and analyzer specification codes" shown in Fig. 2 do not identify whether or not the analyzer used for the assay has a dilution mode. The last column on the right merely includes analyzer codes (B1, U2, B1, U1, H1). Applicant has not defined these codes (B1, U2, B1, U1, H1) any where in the specification as originally filed. Thus, the Examiner asserts these codes do not indicate whether or not the analyzer used for the assay has a dilution mode.

Applicant also points to the page 20, lines 20-23 which states "[t]he assay result stored in the examination information database 12 is examined by the correction determining module 115 to identify whether or not the sample was assayed by an analyzer provided with a dilution mode." The Examiner does not understand how this corresponds to the analyzer identification information for identifying whether or not the analyzer used for the assay has dilution mode. This appears to be a process step performed by the correction determining module 115 (software program) in the control

means, not analyzer information stored in the storage means. The paragraph bridging pages 21-22 of the original specification states the correction determining module 115 identifies whether or not the assay result was assayed by an analyzer provided with a dilution mode, and when the analyzer is not provided with a dilution mode, identifies whether or not the assayed sample was a normal sample or a dilute sample, so as to determine whether or not the correction calculation is necessary. The Examiner asserts this does not pertain to the storage means (i.e., database) configured for storing analyzer identification information.

Applicant's arguments with respect to the previous rejection of claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1 107 159 to Okuno have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. No claims allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797